

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Heraeus Medical Components, LLC  
5030 Centerville Road  
St Paul  
Minnesota  
55127  
USA

Facility ID Number: F000209

Holds Certificate No:

**MDSAP 691199**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.



For and on behalf of BSI:

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Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-07-28

Effective Date: 2020-11-11

Expiry Date: 2022-07-27



BSI Group America Inc. is an MDSAP authorized auditing organization

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...making excellence a habit.™

Certificate No: **MDSAP 691199**

## Registered Scope:

Design, manufacture, and distribution of sterile and non-sterile nitinol and stainless-steel guidewires, sterile and non-sterile retrieval snares and retrieval snare kits.

Contract manufacture of precision components for the medical device industry utilizing molding, coiling, grinding, wire straightening and forming, machining, stamping, coating, laser welding and assembly services.



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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.